

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Seymour Fein

Application No.: 10/706,100

Confirmation No.: 7710

Filed: November 12, 2003

Art Unit: 1654

Title: Pharmaceutical Compositions Including Low
Dosages of Desmopressin

Examiner: Andrew D. Kosar

MAIL STOP PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 35 U.S.C. § 154(b) AND
37 C.F.R. § 1.705(b)**

Sir:

This is a request for reconsideration of the patent term adjustment indicated in the Notice of Allowance of February 23, 2010, for the above-referenced patent application.

In accordance with 37 C.F.R. § 1.705(b)(1), please charge the fee set forth in 37 C.F.R. § 1.18(e), and any other required fees to Deposit Account No. 07-1700, under Order No. SER-001.

Applicant provides the following statement of facts in accordance with 37 C.F.R. § 1.705(b)(2):

37 C.F.R. § 1.705(b)(2)(i)

1. Applicant submits that the correct patent term adjustment under 35 U.S.C. § 154(b), if the patent issues on the date which is the Tuesday that is 28 weeks after the mailing date of the Notice of Allowance, will be 539 days. The basis for the adjustment is as follows:

Under 37 C.F.R. § 1.702(a)(1), the USPTO failed to mail at least one of a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 before the expiration of fourteen months after the date on which the application was filed.

Under 37 C.F.R. § 1.702(a)(2), the USPTO failed to respond to a reply under 35 U.S.C. § 132 or to an appeal taken under 35 U.S.C. § 134 not later than four months after the date on which the reply was filed or the appeal was taken.

Under 37 C.F.R. § 1.702(b), the USPTO failed to issue a patent within three years of the actual filing date of the application.

37 C.F.R. § 1.705(b)(2)(ii), 1.703(a), and 1.703(b)

2. The relevant dates under 37 C.F.R. § 1.703(a)(1) specifying the period of adjustment under 37 C.F.R. § 1.702(a)(1), the relevant dates under 37 C.F.R. § 1.703(a)(2) specifying the period of adjustment under 37 C.F.R. § 1.702(a)(2), and the relevant dates under 37 C.F.R. § 1.703(b) specifying the period of adjustment under 37 C.F.R. § 1.702(b) are as follows:

A. Adjustment under 37 C.F.R. § 1.702(a)(1)

- | | |
|--|-------------------|
| i. Filing date of this application: | November 12, 2003 |
| ii. Day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a): | January 13, 2005 |
| iii. Date of mailing of first action under 35 U.S.C. § 132: | April 24, 2006 |

The number of days in the period beginning on January 13, 2005, and ending on April 24, 2006, is **467 days.**

B. Adjustment under 37 C.F.R. § 1.702(a)(2)

- | | |
|---|--------------|
| i. Date reply to the Final Rejection was filed: | May 16, 2007 |
|---|--------------|

ii. Day after the date that is four months after the date on
which the reply was filed: September 17, 2007

iii. Mailing date of the Non-Final Rejection¹: October 16, 2007

The number of days in the period beginning on September
17, 2007, and ending on October 16, 2007, is **30 days.**

iv. Date reply to the Independent Rule 105 Communication
was filed: August 15, 2008

v. Day after the date that is four months after the date on
which the reply was filed: December 16, 2008

vi. Mailing date of the Final Rejection: January 8, 2009

The number of days in the period beginning on December
16, 2008, and ending on January 8, 2009, is **24 days.**

C. Adjustment under 37 C.F.R. § 1.702(b)

¹ Although a Non-Final Rejection was mailed August 6, 2007, it was subsequently withdrawn on October 16, 2007, and a new Non-Final Rejection was issued because "the Examiner recognized that the previous issued Non-final Office action required further clarification..." (see Office action dated October 16, 2007, page 2, second paragraph). Applicant submits that the withdrawal of a timely Office action and issuance of a new Office action after four months from the date a reply was filed should not be considered timely for the purposes of patent term adjustment. Enactment of 35 U.S.C. § 154 was, in part, to "guarantee... prompt Patent and Trademark Office response" (see, e.g., § 154(b)(A)). Permitting the Office to issue an action within the time limit, only to withdraw the action and replace it with a new action after the expiry of the four month time limit, not only delays prosecution but requires the applicant to restart consideration of the initial Office action in view of the new Office action. The same rationale is used to justify reducing patent term for an applicant who files a supplementary paper after an initial reply, and therefore should also apply to the Office (see Changes to Implement Patent Term Adjustment Under Twenty Year Patent Term, 65 Fed. Reg. 56,372, Col. 3, first paragraph ("The submission of a supplemental reply or other paper (e.g., an information disclosure statement (IDS) or petition) after an initial reply was filed requires the Office to restart consideration of the initial reply in view of the supplemental reply or other paper, which will result in a delay in the Office's response to the initial reply.")). Furthermore, based on a discussion with a member of the Office of Patent Legal Administration, the undersigned understands that when an Office action is withdrawn by a Letter Withdrawing/Vacating Office Action, signed by a Technology Center Director, the withdrawn Office action is not considered to have issued for purposes of patent term adjustment calculation. In the present application, the Office has acted with identical effect in withdrawing the Office action of August 6, 2007, as requiring further clarification and replacing it with the Office action of October 16, 2007. As such, only the Office action of October 16, 2007 would properly be considered in the calculation of patent term adjustment.

- i. Filing date of this application: November 12, 2003
- ii. Day after the date that is three years after the actual filing date of the application: November 13, 2006
- iii. Filing date of a Request for Continued Examination May 16, 2007
- iv. Mailing date of the Notice of Allowance: February 23, 2010
- v. Projected patent issue date which is the Tuesday that is before the date that is 28 weeks after the mailing date of the Notice of Allowance: September 7, 2010

The number of days in the period beginning on November 12, 2003, and ending on September 7, 2010, but not including the number of days beginning on May 16, 2007, and ending on September 7, 2010, is

185 days.

37 C.F.R. § 1.705(b)(2)(iii)

3. Applicant submits the patent to be issued is not subject to a terminal disclaimer.

37 C.F.R. § 1.705(b)(2)(iv)

4. Applicant believes that three circumstances may have constituted a “failure to engage in reasonable efforts to conclude processing or examination” of this application as set forth in 37 C.F.R. § 1.704. The circumstances are as follows:

A. Reduction of Period of Patent Term Adjustment under 37 C.F.R. § 1.704(b)

- i. Date the Non-Final Rejection was mailed to the Applicant: August 2, 2006
- ii. Day after the date that is three months from the mailing date of the Non-Final Rejection: November 3, 2006

iii. Date the reply to the Non-Final Rejection was filed: December 26, 2006

The number of days in the period beginning on November 3, 2006, and ending on December 26, 2006, is **54 days.**

iv. Date the Non-Final Rejection was mailed to the Applicant: October 16, 2007

v. Day after the date that is three months from the mailing date of the Non-Final Rejection: January 17, 2008

vi. Date the reply to the Non-Final Rejection was filed: April 8, 2008

The number of days in the period beginning on January 17, 2008, and ending on April 8, 2008, is **83 days.**

vii. Date the Final Rejection was mailed to the Applicant: January 8, 2009

viii. Day after the date that is three months from the mailing date of the Final Rejection: April 9, 2009

ix. Date the reply to the Final Rejection was filed: May 8, 2009

The number of days in the period beginning on April 9, 2009, and ending on May 8, 2009, is **30 days.**

Applicant submits that all other replies to any notice or action by the USPTO were filed within the three-month period set forth in 37 C.F.R. § 1.704(b).

B. Reduction of Period of Patent Term Adjustment under 37 C.F.R. § 1.704(c)(8)

Applicant believes that the 87 day period beginning on November 9, 2009, with the filing of an Appeal Brief, and ending on February 4, 2010, with the submission of an Information Disclosure Statement (IDS), should not be considered Applicant delay under 37 C.F.R. § 1.704(c)(8), because an Appeal Brief is not considered a “reply” for the purposes of §§ 1.701-1.705, “Adjustment of Patent Term Due to Examination Delay.” In

these sections, the Office consistently distinguishes between a “reply” (see, *e.g.*, § 1.703(a)(2), “reply under § 1.111,” and § 1.703(a)(3), “reply in compliance with § 1.113(c)) and an “appeal brief” (see, *e.g.*, § 1.703(a)(4)). An appeal brief is filed subsequent to a notice of appeal, not in reply to an Office action. Interpreting an IDS filed after an appeal brief as a “supplemental reply or other paper [filed]... after a reply” is inconsistent with the plain language of the rules.

Further, Applicant does not believe the submission of the IDS was a failure to engage in reasonable efforts to conclude prosecution, because submission of the IDS did not slow prosecution. Applicant encloses herewith a copy of the Information Disclosure Statement submitted to the Office on February 4, 2010, marked as “Exhibit A.” In the second paragraph of this Information Disclosure Statement, Applicant indicated that “Applicants understand that, although this application is currently under appeal, this submission and the listed references will be expressly considered if and when prosecution is reopened.” Applicant submits that the filing of an Information Disclosure Statement while an Appeal is pending, to be considered when prosecution reopens, does not slow the prosecution of the application, because it does not “require[] the Office to restart consideration of the initial reply in view of the supplemental reply” (see *Changes to Implement Patent Term Adjustment Under Twenty Year Patent Term*, 65 Fed. Reg. 56,372, Col. 3, first paragraph). When prosecution reopens, an Examiner will not have to restart consideration of the Appeal Brief in view of the IDS; the filing of an IDS after an Appeal Brief is therefore not a failure to engage in reasonable efforts to conclude prosecution.

Finally, as indicated in the Examiner-Initiated Interview Summary mailed with the Notice of Allowance on February 23, 2010, the Examiner telephoned the undersigned on January 29, 2010, to discuss claim amendments that would place the claims in condition for allowance. Applicant’s Information Disclosure Statement was filed six days later on February 4, 2010, and considered by the Examiner the same day. The Examiner contacted the undersigned the next day, February 5, 2010, at which time an agreement relating to claim amendments was reached. Applicant respectfully submits that the filing of the Information Disclosure Statement on February 4, 2010, did not slow

the prosecution of the application, and therefore is not a failure to engage in reasonable efforts to conclude prosecution.

37 C.F.R. § 1.705(b)(2)(ii) and 1.703(f)

5. The period of delay attributable to the grounds specified in 37 C.F.R. § 1.702(a)(1), which begins on January 13, 2005, and ends on April 24, 2006, and the period of delay attributable to the grounds specified in 37 C.F.R. § 1.702(b), which begins on November 13, 2006, and ends on May 16, 2007, do not overlap. Further, the periods of delay attributable to the grounds specified in 37 C.F.R. § 1.702(a)(2), the first of which begins on September 17, 2007, and ends on October 16, 2007, and the second of which begins on December 16, 2008, and ends on January 8, 2009, do not overlap with the period of delay attributable to the grounds specified in 37 C.F.R. § 1.702(b), which begins on November 13, 2006, and ends on May 16, 2007. The adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent will be entitled will be the period of 467 days calculated under 37 C.F.R. § 1.703(a)(1), plus the sum of the 30 and 24 day periods calculated under 37 C.F.R. § 1.703(a)(2), plus the predicted period of 185 days calculated under 37 C.F.R. § 1.703(b), less the sum of the 54, 83, and 30 day periods calculated under 37 C.F.R. § 1.704.

Accordingly, Applicant submits that the patent will be entitled to a patent term adjustment of $467 + 30 + 24 + 185 - 54 - 83 - 30 = \underline{539}$ days, running from the expiration date of the patent as set forth in 35 U.S.C. § 154(a)(2).

If for any reason, this Petition is found not to comply with the requirements of 37 C.F.R.
§ 1.705, or is otherwise found improper, please call the undersigned agent.

Respectfully submitted,

Date: May 20, 2010

/Megan A. Gustafson/
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Docket No.: SER-001
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Seymour Fein

Application No.: 10/706,100

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Art Unit: 1654

For: Pharmaceutical Compositions Including Low
Dosages of Desmopressin

Examiner: A. D. Kosar

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants understand that, although this application is currently under appeal, this submission and the listed references will be expressly considered if and when prosecution is reopened. Please charge any required fee to our Deposit Account No. 07-1700, under Order No. SER-001.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

Additionally, Applicants wish to inform the Examiner of the following U.S. patent application, its claims, and the contents of its prosecution file:

Application Number	Filing Date	Art Unit
12/613,855	November 6, 2009	1654

The Examiner is respectfully requested to consider the listed references.

Dated: February 4, 2010

Respectfully submitted,

/Brian A. Fairchild/

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